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Suppressing Generic Drugs Fleeces Consumers (and Lets the FDA off the Hook)

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Common Cause, a special interest watchdog, estimates government suppression of generics costs Americans $550 million a year in higher prices for prescriptions.

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Brand name pharmaceutical companies and federal and state governments are raiding consumers' pocketbooks by preventing them from buying generic drugs. Such restrictions can be an enormous financial drain, especially for low-income Americans and seniors who live on fixed incomes and pay for prescriptions out-of-pocket.

Generic drugs offer consumers more choices and keep prices down by competing with brand name pharmaceuticals, often at savings of 30 percent to 60 percent.[1] When government restricts access to generics, it forces consumers either to buy brand name drugs, which can cost one and a half to three times more, or to do without treatment altogether. This restriction also means higher costs for employers and unions (who provide health benefits); taxpayers (who fund government health programs); and individual consumers (especially seniors). According to Common Cause, a watchdog group that examines the influence of special interests on politics, government suppression of generics is costing Americans $550 million a year, hidden in higher prices for prescriptions.[2]

In effect, government restrictions on generics are hidden taxes that directly benefit brand name pharmaceutical companies. These companies lobby for restrictions on generics to offset the high costs imposed on brand names by the federal Food and Drug Administration (FDA). These companies also seek monopoly rents through lobbying for patent extension. Patents were intended to reward and encourage innovation. Extending patents that have already been granted do not create any additional incentives to innovate.

Michael F. Cannon authored this paper while a health care policy analyst at Citizens for a Sound Economy Foundation.

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[1] "Sneak Prescription Drug Patent Extension in Appropriations Rider Would Increase Drug Prices for Seniors," Public Citizen press release, October 9, 1998.

[2] "Pocketbook Politics: How Special-Interest Money Hurts the American Consumer," *Common Cause News*, February 24, 1998.

The Voice of Consumers for Free Enterprise

SUPPRESSING CONSUMER ACCESS TO GENERICS

1. Extending Government-Granted Monopolies Keeps Generics Off the Market

- The federal government grants monopolies (20-year patents and periods of market exclusivity) to makers of new drugs, after which others may market generic versions. Much of that time is consumed getting the FDA's approval to market a new drug. Some argue the remaining monopoly period is not enough time to recoup the necessary investment, and therefore should be extended.

- One manufacturer spent over $1.5 million in the first half of 1998 to persuade Congress to extend one of their monopolies because their drug "was stuck in the [FDA] pipeline for . . . double the normal review time. All the drug company wants back is that lost time[.]"[3]

- However, it is the Food and Drug Administration's (FDA) lengthening approval process (now 15 years, up from eight years in the 1960s)[4] that eats up patent time. Extending monopolies merely hides that fact, shielding brand names from the cost of that "lost time" by passing it on to consumers. The root of the problem – the FDA's costly review process – is not addressed.

- One pharmaceutical giant has blocked generic versions of a highly effective cancer therapy by securing separate patents for different uses and ways of administering the drug — despite the fact that the government developed the drug at taxpayer expense.[5]

2. Holding up FDA Approval of Generics

- Brand names routinely file patent infringement lawsuits and FDA "citizens' petitions," which halt FDA consideration of generic rivals.

- Many "citizens' petitions" are frivolous (the FDA has rejected 83 percent of those filed against generics since 1990), yet can add years to a generics' approval time.[6]

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[3]Bill McAllister, "A Capital Way to Stop a Headache," *The Washington Post*, October 15, 1998, p. A21.

[4]Joseph A DiMasi, Ph.D., *et al.*, "New Drug Development in the United States from 1963 to 1992," *Clinical Pharmacology & Therapeutics*, 55(6):609-22, June 1994.

[5]Li Fellers, "Taxol Is One of the Best Cancer Drugs Ever Discovered by the Federal Government. Why Is It Beyond Some Patients' Reach?" *The Washington Post Magazine*, May 31, 1998, p. W10.

[6]Burton, *op. cit.*

- Brand names often sue for patent infringement even if the generic firm has no intention of going to market before the patent expires.

- The first generic to file for FDA approval can block out other generics for six months. Some brand names actually pay generic firms to delay this limited exclusivity period, which gives the brand name a longer period of complete exclusivity.[7]

3. Keeping Generics off Government Formularies

- Medicaid and Medicare have approved lists of prescription drugs, called a "formulary." Brand name manufacturers often try to keep generics off these formularies.

- In 1997, a pharmaceutical company filed a petition with the Massachusetts Drug Formulary Commission in an attempt to block the substitution of a generic version of their anticoagulant drug – a drug whose patent expired over thirty years ago, and whose price has increased by more than 400 percent.[8]

4. "Notification" and Other Regulatory Obstacles to Generics

- As a result of an ever-more-powerful regulatory regime, many pharmaceutical companies have found it more effective to shift their efforts to seeking profits through regulation, not competition.

- Brand name firms pressure state legislatures and Boards of Pharmacy to erect obstacles for patients who want generics.

- "Notification" laws require pharmacists to contact the prescribing physician before they make a generic substitution, despite the fact that physicians already may prevent substitution if they wish. According to an FDA official, a notification requirement "effectively blocks generics" because a pharmacist "can't call all the physicians."[9]

- One pharmaceutical giant hired a public relations firm to form a "patients' coalition" and launch a state-by-state campaign for "notification" laws to protect its market share of a blockbuster anti-coagulant. Where enacted, "notification" has driven generic market share below 8 percent, compared to 25 percent elsewhere. The firm alleges generics may not be equivalent to the original, a claim the FDA denounces as "false and misleading."[10]

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[7] *Ibid.*.

[8] "DuPont Merck petition fails to block Barr's generic Coumadin anti-coagulant," *AFX News*, November 19, 1997.

[9] Burton, *op.cit.*

[10] *Ibid.*.

Market Efficiency or Regulatory Profit? Blockbuster drugs can gross over $1 million in sales per day. Each day a firm extends its monopoly — each way it uses government to block its competitors — can mean millions in additional profits. Yet businesses that use the government to hurt their competitors make money at the expense of consumers, whose choices they restrict. Their profits are not a reflection of their value to society, but are in fact a measure of the cost of regulation. In this case, two factors drive the costs of regulation.

First, government constantly increases the cost of developing new medicines. The amount of time (15 years) and money (now $500 million) necessary to win approval of a new medicine continues to grow because the FDA is not held accountable for making patients wait too long or spend too much for prescription drugs.

Second, convincing the government to regulate your competition is easier than convincing government to stop regulating you. Brand name firms are wary of angering the FDA with its $1 billion budget and power to bankrupt firms by slowing its review of their products. On the other hand, joining forces with government allows brand name firms to pass costs along to less organized interests (patients and other payers) and potential competitors (generics). Ultimately, this is a shortsighted strategy that creates an expanded FDA with more regulatory oversight.

Consumers should press both lawmakers and the pharmaceutical industry to curb the ever-expanding FDA bureaucracy.

It may be that brand names are not adequately rewarded for their investment in new medicines. But allowing them to shake down consumers for millions of dollars is not the answer. If makers of pioneer drugs are unable to make a profit without using government to block their competition, perhaps it is time to reexamine the costs the FDA imposes on these innovators.

Before government and the pharmaceutical industry injure more patients with further regulation, consumers should press both lawmakers and industry to curb the ever-expanding FDA bureaucracy.

Consumers should push for reforms that increase the resources available for drug approvals without sacrificing high safety standards. Private institutions (such as medical schools, peer-reviewed medical journals and the *U.S. Pharmacopeia*) already certify the safety and efficacy of "off-label" drug therapies. Congress should strengthen this process, eliminating the FDA's ban on "off-label" medical speech. Further, Congress should outsource initial FDA reviews to these and other private institutions (*e.g.* Underwriter's Laboratories, medical associations). These reforms would also lower the regulatory costs imposed on brand name and generic firms, but most of all, on consumers.